

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA,

Plaintiff,

v.

EUROLINE FOODS, LLC; ROYAL SEAFOOD
BAZA, INC.; EDUARD SHNAYDER;
SYOMA SHNAYDER; ALBERT NIYAZOV;
AND OLEG POLISCHOUK,

Defendants.

Civil Action No. 18-cv-2879 (BMC)

**DEFENDANTS' ANSWER AND AFFIRMATIVE AND OTHER DEFENSES
TO PLAINTIFF'S COMPLAINT**

Defendants Euroline Foods, LLC; Royal Seafood Baza, Inc.; Eduard Shnayder; Syoma Shnayder; Albert Niyazov; and Oleg Polischouk (collectively "Defendants"), by and through their undersigned counsel, hereby file their Answer and Affirmative and Other Defenses to Plaintiff's Complaint.

1. Paragraph 1 contains Plaintiff's legal and factual characterizations of this action, to which no response is required. To the extent that a response may be deemed necessary, Defendants admit that Plaintiff's action is brought to compel compliance with the federal Food, Drug, and Cosmetic Act ("Act"), but deny they that have not already complied with the Act.

Jurisdiction and Venue

2. Paragraph 2 states legal conclusions, to which no response is required. To the extent that a response may be deemed necessary, Defendants deny the allegations.

3. Paragraph 3 states legal conclusions, to which no response is required. To the extent that a response may be deemed necessary, Defendants deny the allegations.

Defendants

4. Defendants admit the allegations in Paragraph 4, except to the extent that Paragraph 4 states legal conclusions regarding this Court's jurisdiction, to which no response is required. To the extent that a response to these jurisdictional allegations may be deemed necessary, Defendants deny the allegations.

5. Defendants deny the allegations in the last sentence of Paragraph 5. Defendants admit the remaining allegations in Paragraph 5, except to the extent that they state legal conclusions regarding this Court's jurisdiction, to which no response is required. To the extent that a response to these jurisdictional allegations may be deemed necessary, Defendants deny the allegations.

6. Defendants admit the allegations in Paragraph 6, except to the extent that they state legal conclusions regarding this Court's jurisdiction, to which no response is required. To the extent that a response to these jurisdictional allegations may be deemed necessary, Defendants deny the allegations.

7. Defendants admit the allegations in Paragraph 7, except to the extent that they suggest that Defendant Syoma Shnayder is a woman, and except to the extent that they state legal conclusions regarding this Court's jurisdiction, to which no response is required. To the extent that a response to these jurisdictional allegations may be deemed necessary, Defendants deny the allegations.

8. Defendants admit the allegations in the first, third, and fourth sentences of Paragraph 8, except to the extent that they state legal conclusions regarding this Court's jurisdiction, to which no response is required. To the extent that a response to these jurisdictional allegations may be deemed necessary, Defendants deny the allegations.

Defendants further deny as unduly vague and incomplete the allegation that Defendant Niyazov is “responsible for preventing, detecting, and correcting objectionable practices and conditions.”

9. Defendants admit the allegations in Paragraph 9, except to the extent that they state legal conclusions regarding this Court’s jurisdiction, to which no response is required. To the extent that a response to these jurisdictional allegations may be deemed necessary, Defendants deny the allegations.

10. Defendants deny that they currently prepare and process any products. Plaintiffs admit the remaining allegations in Paragraph 10.

11. Defendants admit the allegations in Paragraph 11.

Food Safety

12. Defendants lack knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 12 and therefore deny the same.

13. Defendants lack knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 13 and therefore deny the same.

14. Defendants lack knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 14 and therefore deny the same.

15. Defendants lack knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 15 and therefore deny the same.

16. Defendants lack knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 16 and therefore deny the same.

17. Paragraph 17 states legal conclusions, to which no response is required. To the extent that a response may be deemed necessary, Defendants deny the allegations.

18. Defendants lack knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 18 and therefore deny the same.

19. Defendants lack knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 19 and therefore deny the same.

20. Paragraph 20 states legal conclusions, to which no response is required. To the extent that a response may be deemed necessary, Defendants deny the allegations.

Regulatory Framework

21. Paragraph 21 states legal conclusions, to which no response is required. To the extent that a response may be deemed necessary, Defendants deny the allegations.

22. Paragraph 22 states legal conclusions, to which no response is required. To the extent that a response may be deemed necessary, Defendants deny the allegations.

23. Paragraph 23 states legal conclusions, to which no response is required. To the extent that a response may be deemed necessary, Defendants deny the allegations.

24. Paragraph 24 states legal conclusions, to which no response is required. To the extent that a response may be deemed necessary, Defendants deny the allegations.

25. Paragraph 25 states legal conclusions, to which no response is required. To the extent that a response may be deemed necessary, Defendants deny the allegations.

26. Paragraph 26 states legal conclusions, to which no response is required. To the extent that a response may be deemed necessary, Defendants deny the allegations.

27. Paragraph 27 states legal conclusions, to which no response is required. To the extent that a response may be deemed necessary, Defendants deny the allegations.

28. Paragraph 28 states legal conclusions, to which no response is required. To the extent that a response may be deemed necessary, Defendants deny the allegations.

29. Paragraph 29 states legal conclusions, to which no response is required. To the extent that a response may be deemed necessary, Defendants deny the allegations.

Defendants' Alleged Violations

30. Paragraph 30 states legal conclusions, to which no response is required. To the extent that a response may be deemed necessary, Defendants deny the allegations.

31. Paragraph 31 states legal conclusions, to which no response is required. To the extent that a response may be deemed necessary, Defendants deny the allegations.

32. Paragraph 32 states legal conclusions, to which no response is required. To the extent that a response may be deemed necessary, Defendants deny the allegations.

Allegations Regarding History of Violations

33. Defendants deny the allegations in Paragraph 33, except to admit that the Food and Drug Administration (“FDA”) inspected certain facilities owned by Euroline Foods, LLC and Royal Seafood Baza, Inc. in March 2015, February-March 2016, and November-December 2016, and that FDA conducted a follow-up investigation in November 2017.

34. Defendants admit the allegations in the first sentence of Paragraph 34. Defendants deny the allegations in the second sentence of Paragraph 34.

35. Defendants admit that in March 2015, FDA investigators issued to Defendant Niyazov a written List of Inspectional Observations (“Form FDA 483”). The remaining allegations in Paragraph 35 purport to characterize the Form FDA 483, which is a document that speaks for itself, and Defendants deny Plaintiff’s characterization and interpretation of the same.

36. Defendants admit the allegations in the first sentence of Paragraph 36, and further admit that on or about October 20, 2015, FDA issued a Warning Letter to Defendant Shnayder. The remaining allegations in Paragraph 35 purport to characterize the Warning Letter, which is a

document that speaks for itself, and Defendants deny Plaintiff's characterization and interpretation of the same.

37. Defendants admit that in March 2016, FDA investigators issued to Defendant Niyazov a Form FDA 483. The remaining allegations in Paragraph 37 purport to characterize the Form FDA 483, which is a document that speaks for itself, and Defendants deny Plaintiff's characterization and interpretation of the same.

38. Defendants deny the allegations in Paragraph 38 as unduly vague and incomplete, except to admit that in March 2015 and March 2016, FDA investigators presented Defendant Niyazov with a Form FDA 483. Defendants further deny that there were any "objectionable conditions" at their facility.

39. Defendants admit that Defendant Niyazov sent written responses to FDA's Form FDA 483 and Warning Letter. The remaining allegations in Paragraph 39 purport to characterize those responses, which are documents that speak for themselves, and Defendants deny Plaintiff's characterization and interpretation of the same.

40. Defendants deny the allegations in the first sentence of Paragraph 40. Defendants admit that FDA issued to Defendant Niyazov a Form FDA 483 on December 6, 2016. The remaining allegations in Paragraph 40 purport to characterize the Form FDA 483, which is a document that speaks for itself, and Defendants deny Plaintiff's characterization and interpretation of the same.

41. Defendants deny the allegations in the first and second sentences of Paragraph 41. Defendants deny the allegations in the third sentence of Paragraph 41 as unduly vague and incomplete.

42. Defendants admit the allegations in Paragraph 42.

43. Defendants admit the allegations in the first sentence of Paragraph 43.

Defendants deny the allegations in the second sentence of Paragraph 43.

44. Defendants lack knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 44 and therefore deny the same. Defendants further deny that there were HACCP and cGMP deficiencies at their facilities.

45. Defendants deny the allegations in the first sentence of Paragraph 45. The remaining allegations in Paragraph 45 state legal conclusions, to which no response is required. To the extent that a response may be deemed necessary, Defendants deny the allegations.

46. Paragraph 46 states legal conclusions, to which no response is required. To the extent that a response may be deemed necessary, Defendants deny the allegations.

47. Defendants lack knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 47 regarding the beliefs of the United States and therefore deny the same. Defendants further deny that they have violated the law.

Defendants deny that Plaintiff is entitled to a judgment or any other relief requested in its “WHEREFORE” paragraphs following Paragraph 47 of the Complaint.

AFFIRMATIVE AND OTHER DEFENSES

Defendants deny each and every allegation contained in Plaintiff’s Complaint—including in all headers and footnotes—that are not specifically admitted herein.

FIRST

The Complaint fails to state a claim upon which relief can be granted.

SECOND

The claims in the Complaint are barred because any cGMP deficiencies were not material.

THIRD

Any and all actions taken by Defendants with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

FOURTH

The claims in the Complaint are barred because Defendants have complied with all applicable regulations of the federal government.

FIFTH

Neither the United States nor any state or municipality has suffered, and they will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of the Defendants as alleged in the Complaint.

SIXTH

Defendants have not knowingly or intentionally waived any applicable defenses and explicitly reserve the right to assert and rely on such other applicable defenses as may become available or apparent during discovery. Defendants further reserve the right to amend their Answer and/or defenses accordingly, and/or to delete defenses that they determine are not applicable during the course of discovery.

JURY TRIAL DEMANDED

Defendants hereby demand a trial by jury on all counts so triable.

PRAYER FOR RELIEF

WHEREFORE, having stated their answer and affirmative and other defenses,

Defendants pray for relief as follows:

1. That Plaintiff take nothing under the Complaint, and the Complaint be dismissed with prejudice;
2. That judgment be entered in favor of Defendants and against Plaintiff on each and every cause of action set forth in the Complaint;
3. That Defendants recover their costs of suit and attorneys' fees incurred herein; and
4. That Defendants be granted such other and further relief as the Court deems just and proper.

Dated: July 11, 2018

Respectfully submitted,

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